

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

NOV 1 6 2000

Duncan Hynd Associates, Ltd c/o Diana Upton 719 Catalpa Avenue Teaneck, NJ 07666 Re: K002608

Invac System (Patient Immobilization System

for Radiation Therapy)
Dated: August 15, 2000
Received: August 22, 2000

Regulatory class: II

21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Upton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D. Captain, USPHS

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

	510(k) Number (if know	wn) KO	02608	· · · · · · · · · · · · · · · · · · ·
	Inv. Device Name:	ac System - for p	atient immobilization	
	Indications for Use:			
	vacuum bags, a p Invac offers the offorming and maineded to keep p treatments over provides previous bags. The auto-sbags and switches for the patient. In the bags so the made of Platilon extreme elongatiand abrasion ressuch as rubber of and inertness	pump and an autoperator enhance intaining of high patients in exactly long periods of tissly unattainable sensing unit autopes on the interna. The auto-sensing at maximum accion and very high sistance. Platilon r plastic synthetics.	immobilization system in so-sensing vacuum supped control and reliability precision vacuum mold y the same position for me. Invac's auto-sensing levels of moldability of matically monitors the levels of maintain the gunit prevents any unduracy is achieved. Invalues in tear propagate surpasses comparable ics in terms of flexibility	ort system. y in the s that are repeated ng unit the vacuum vacuum in the correct mold ue distortion c bags are ke elasticity, ation strength materials y, durability
	(PLEASE DO NOT WRIT	E BELOW THIS L	INE - CONTINUE ON AN	OTHER PAGE)
	Concurrence of CDRH, Office of Device Evaluation (ODE)			
	Prescription Use	OR	Over-the-Counter Use	
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<u>Jánn</u> (Division S	d la Segram	_	(Optional Forma	t 1/2/96)
Division of	Reproductive, Abdominal, ENT,	•		
	ogical Devices	4.3	3	
510(k) Nun	nber K002(608			